

## II. LISTING OF THE CLAIMS

The claims have not been amended. This listing of claims is being provided for the Examiner's convenience.

Claim 1.(currently amended): A solid controlled release oral dosage form, comprising, a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a normal release matrix,  
said matrix overcoated with a controlled release coating comprising a polymethacrylate or a water insoluble cellulose,  
 said dosage form providing a therapeutic effect for at least about 24 hours.

Claim 42.(currently amended): The controlled release dosage form as claimed in claim 1, wherein said ~~matrix is a controlled release matrix~~ coating comprises a polymethacrylate.

Claim 43.(currently amended): The controlled release dosage form as claimed in claim 1, wherein said ~~matrix is overcoated with a controlled release coating~~ comprises a water insoluble cellulose.

Claim 44.(currently amended): The controlled release dosage form as claimed in claim 42 43, wherein said ~~matrix is a normal release matrix~~ controlled release coating further comprises a water soluble cellulose.

Claim 45.(currently amended): The controlled release dosage form as claimed in claim 43, wherein said ~~matrix is a controlled release matrix~~ controlled release coating further comprises a polyvinylpyrrolidone.

Claim 46.(previously presented): The controlled release dosage form as claimed in claim 1, containing from about 50 to 800mg of tramadol or a pharmaceutically acceptable salt thereof, calculated as the hydrochloride salt.

Claim 47.(previously presented): The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 50% tramadol released after 1 hour; from about 0 to about 75% tramadol released after 2 hours; from about 10 to about 95% tramadol released after 4 hours; from about 35 to about 100% after 8 hours; from about 55 to about 100% tramadol released after 12 hours; from about 70 to about 100% tramadol released after 16 hours; and greater than 90% tramadol released after 24 hours, by weight.

Claim 48.(previously presented): The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 30% tramadol released after 1 hour; from about 0 to about 40% tramadol released after 2 hours; from about 3 to about 55% tramadol released after 4 hours; from about 10 to about 65% after 8 hours; from about 20 to about 75% tramadol released after 12 hours; from about 30 to about 88% tramadol released after 16 hours; from about 50 to about 100% tramadol released after 24 hours and greater than 80% tramadol released after 36 hours, by weight.

Claim 49.(previously presented): The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 15 to about 25% tramadol released after 1 hour; from about 25 to about 35% tramadol released after 2 hours; from about 30 to about 45% tramadol released after 4 hours; from about 40 to about 60% after 8 hours; from about 55 to about 70% tramadol released after 12 hours; and from about 60 to about 75% tramadol released after 16 hours, by weight.

Claim 50.(previously presented): The dosage form according to claim 1, which provides a  $t_{\max}$  from about 3 to about 6 hours.

Claim 51.(previously presented): The dosage form according to claim 1, which provides a  $W_{50}$  from about 10 to about 33 hours.

Claims 52-62. (cancelled)

Claim 63. (new): The dosage form according to claim 43. wherein said water insoluble cellulose comprises ethylcellulose.

Claim 64. (new): The dosage form of claim 1, comprising 100 mg tramadol hydrochloride.

Claim 65. (new): The dosage form of claim 1, comprising 200 mg tramadol hydrochloride.

Claim 66. (new): The dosage form of claim 1, comprising 300 mg tramadol hydrochloride.

Claim 67. (new): The dosage form of claim 1, comprising 400 mg tramadol hydrochloride.

Claim 68. (new): The dosage form of claim 1, comprising 600 mg tramadol hydrochloride.

Claim 69. (new): The dosage form of claim 42, comprising 100 mg tramadol hydrochloride.

Claim 70. (new): The dosage form of claim 42, comprising 200 mg tramadol hydrochloride.

Claim 71. (new): The dosage form of claim 42, comprising 300 mg tramadol hydrochloride.

Claim 72. (new): The dosage form of claim 42, comprising 400 mg tramadol hydrochloride.

Claim 73. (new): The dosage form of claim 42, comprising 600 mg tramadol hydrochloride.

Claim 74. (new): The dosage form of claim 43, comprising 100 mg tramadol hydrochloride.

Claim 75. (new): The dosage form of claim 43, comprising 200 mg tramadol hydrochloride.

Claim 76. (new): The dosage form of claim 43, comprising 300 mg tramadol hydrochloride.

Claim 77. (new): The dosage form of claim 43, comprising 400 mg tramadol hydrochloride.

Claim 78. (new): The dosage form of claim 43, comprising 600 mg tramadol hydrochloride.